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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/812,232	03/29/2004	Wei Liu	01997.026700	3082

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EXAMINER	
MONDESI, ROBERT B	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/812,232	LIU ET AL.	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.00

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, drawn to an isolated nucleic acid molecule, a host cell transformed or transected with an isolated nucleic acid molecule, an isolated nucleic acid molecule operable linked to at least an expression control sequence, an anti-sense oligonucleotide complementary to an mRNA corresponding to a nucleic acid molecule, classified in class 536, subclass 23.1.

II. Claims 19-20, drawn to an isolated protein, classified in class 530, subclass 350.

III. Claim 21-22, drawn to an antibody capable of binding to a protein, classified in class 530, subclass 387.1.

IV. Claims 23-24, drawn to nonhuman transgenic animal, classified in class 800 subclass 8.

V. Claims 25-28, drawn to a method of inhibiting Cot/Tp12-induced ERK activation in a cell population comprising transforming or transfecting said population with a nucleic acid molecule, classified in class 514, subclass 44.

VI. Claims 29-30, drawn to a method of inhibiting NF-κB mediated gene expression in a in a cell population comprising transforming or transfecting

said population with a nucleic acid molecule, classified in class 514, subclass 44.

VII. Claims 31-32, drawn to a method of inhibiting IL-8 production in a cell population comprising transforming or transfecting said cell population with a nucleic acid molecule.

VIII. Claims 33-34, drawn to a method of inhibiting the expression of KSR-2 in a cell population comprising treating said cell population with the an antisense oligonucleotide.

IX. Claims 35-40, drawn to a method of identifying a compound capable of inhibiting or increasing the activity of KSR-2 protein comprising, a) contacting a first sample containing the KSR-2 protein with one of a plurality of test compounds; and

(b) comparing the activity of the KSR-2 protein in the first contacted sample with that of the KSR-2 protein in a second sample not contacted with the test compound, wherein a decrease in the activity of the KSR-2 protein in the first sample, as compared with that in the second sample, identifies the compound as an inhibitor of KSR-2 protein activity.

X. Claims 41-43 a method of inhibiting expression of KSR-2 in a cell population comprising treating said cell population with a siRNA molecule targeted to a mRNA corresponding to an isolated nucleic acid.

XI. Claims 44-45 a siRNA molecule that inhibits the expression of KSR-2 .

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the Claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The nucleic acid of Invention I and the antibody of Invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these Inventions are distinct.

Inventions I and IV, I and XI, II and IV, II and XI, III and IV, III and XI, IV and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects the invention of Group I is an isolated nucleic acid molecule, a host cell transformed or transected with an isolated nucleic acid molecule, an isolated nucleic acid molecule operable linked to at least an expression control sequence, an anti-sense

oligonucleotide complementary to an mRNA corresponding to a nucleic acid molecule which can be used to make a probe, the invention of Group II is a protein that can be used in an assay to make anti-bodies, the invention of Group III is an antibody that is used in the detection of antigens or in an immunoassay, the invention of Group IV is a transgenic animal that can be used in the study of diseases and the production of proteins, the invention of Group XI is a siRNA molecule that inhibits the expression of KSR-2.

Inventions I and V, I and VI, I and VII, I and VIII, are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different method such as the process of making a nucleic acid probe or the expression of recombinant proteins.

The product of the invention of Group I is not used in the methods of Groups IX and X and thus patentably distinct.

The product of the inventions of Groups II, III and IV are not used in the methods of Groups V, VI, VII, VIII and X and thus patentably distinct.

Inventions II and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as the process of making anti-bodies.

The product of the inventions of Groups III and IV are not used in the method of Group X and thus patentably distinct.

Inventions V and VI-X, VI and VII-X, VIII and IX-X, IX and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions, and different effects. The invention of Group V is a method of inhibiting Cot/Tp12-induced ERK activation in a cell population comprising transforming or transfecting said population with a nucleic acid molecule, the invention of Group VI is a method of inhibiting IL-8 production in a cell population comprising transforming or transfecting said cell population with a nucleic acid molecule, the invention of Group VII is a method of inhibiting IL-8 production in a cell population comprising transforming or transfecting said cell population with a nucleic acid molecule, the invention of Group VIII is a a method of identifying a compound capable of inhibiting or increasing the activity of KSR-2 protein comprising, a) contacting a first sample containing the KSR-2 protein with one of plurality of test compounds; and (b) comparing the activity of the KSR-2 protein in the first contacted sample with that of the KSR-2 protein in a second sample not contacted with the test compound, wherein a decrease in the activity of the KSR-2 protein in the first sample, as compared with that

in the second sample, identifies the compound as an inhibitor of KSR-2 protein activity, the invention of Group X is a method of inhibiting expression of KSR-2 in a cell population comprising treating said cell population with a siRNA molecule targeted to a mRNA corresponding to an isolated nucleic acid.

Inventions X and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as the process of nucleic acid probes.

The product of the invention of Group XI is not used in the method of Groups V, VI, VII, VIII and IX and thus is patentably distinct.

Restriction Requirement Applicable to all Groups

Furthermore, in **claims 1-2, 7-20, 23-24** the presence of multiple polynucleotide sequences, each with a different SEQ ID NO: allows for a variety of patentably distinct products. Depending on the sequence of each polynucleotide, the characteristics of the resulting molecule will vary in regards to structure and function. Each one of these polynucleotides is capable of hybridizing to different probes and is capable of encoding a characteristically different peptide in regards to structure and activity. Therefore these polypeptides and polynucleotides are patentably distinct absent factual evidence to the contrary. Applicant is required under 35 U.S.C. 121 to elect a single SEQ ID NO: for prosecution on the merits.

Applicant is advised that a reply to this requirement must include an identification of SEQ ID NO: that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. The applicant should be aware that selection of a single SEQ ID NO: represents a response to a restriction requirement, not an election of species.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and search, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert B. Mondesi
07/25/05

JON WEBER
SUPERVISORY PATENT EXAMINER